

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
CAMDEN VICINAGE**

IN RE : **MASTER DOCKET NO.:**
PAULSBORO DERAILMENT CASES : **13-CV-784 (RBK/KMW)**

JACOB SMITH *et al.* : CASE NO: 1:13-CV-07410-RBK-KMW
Plaintiffs, :
v. :
CONSOLIDATED RAIL :
CORPORATION, *et al.*, :
Defendants. :

**DEFENDANTS CONSOLIDATED RAIL CORPORATION, NORFOLK SOUTHERN
RAILWAY COMPANY AND CSX TRANSPORTATION, INC.'S
REPLY MEMORANDUM OF LAW IN SUPPORT OF MOTION TO EXCLUDE THE
EXPERT REPORT AND TESTIMONY OF ROBERT LAUMBACH, M.D., M.P.H., C.I.H.**

Filed on behalf of Defendants,
Consolidated Rail Corporation,
Norfolk Southern Railway Company
and CSX Transportation, Inc.

Counsel of Record for This Party:

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COME NOW Defendants, Consolidated Rail Corporation, Norfolk Southern Railway Company and CSX Transportation, Inc. ("Defendants"), by and through their counsel, Burns White LLC, and submit this Reply Memorandum of Law in Support of their Motion to Exclude the Expert Report and Testimony of Robert Laumbach, M.D., M.P.H., C.I.H.

I. PRELIMINARY STATEMENT

Plaintiff, Ryan Ragone, has failed to satisfy his burden of demonstrating that Dr. Laumbach's opinions and methodology satisfy the requirements of *Daubert* and Fed. R. Evid. 702. As an initial matter, Plaintiff's Opposition includes a declaration of Dr. Laumbach that

blatantly attempts to fill the holes in his opinions - an implicit admission that his methodology for determining causation in this matter is lacking. However, Dr. Laumbach's declaration has been submitted in contravention of the rules and should be disregarded.

Further, Plaintiff's suggestion that any deficiencies in Dr. Laumbach's opinions are better left to cross examination ignores controlling law. As this Court is aware, it must serve as a gatekeeper to insure that expert evidence is reliable. An analysis of Dr. Laumbach's proffered opinions and underlying methodologies, which *Daubert* mandates, reveals his speculative opinion that Plaintiff's brief, acute exposure to vinyl chloride caused or exacerbated the medical problems allegedly suffered by Plaintiff, as well as the need for medical monitoring, is unreliable and unsupported.

II. LAW AND ARGUMENT

A. Dr. Laumbach Relies On The NTSB Report, Contrary To 49 U.S.C. § 1154(b).

Plaintiff's Opposition is an exercise in avoidance. It blatantly ignores the cases cited in Defendants' motion holding that an expert cannot rely upon information contained in an NTSB report. *See Louisiana ex rel. Dept. of Transp. & Dev. v. Kition Shipping Co., Ltd.*, 653 F.Supp.2d 633, 647-48 (M.D. La. 2009); *Credle v. Smith and Smith, Inc.*, 42 F. Supp. 3d 596 (D.N.J. 2013). Nothing can be clearer than the Congressional mandate of 49 U.S.C. § 1154(b), which prohibits the use of an NTSB report. Accordingly, this Court recently granted Defendants' Motion to Strike the NTSB Report in its entirety in related Paulsboro derailment proceedings. *See* July 9, 2015 Order (Case 1:13-cv-00784-RBK-KMW Doc. 848). Plaintiff's veiled attempt to introduce parts of the report through her expert is merely a "back door" attempt to circumvent the statute. *Dowe v. National Railroad Passenger Corp.*, 2004 WL 887410 at *6 (N.D. Ill. April 26, 2004).

Plaintiff's assertion that Dr. Laumbach's reliance on the NTSB report was merely a "casual reference," or otherwise permissible because he also relied on "a mountain of other exposure-levels evidence," is wholly without merit. Pl. Opp. at 2. Not only does Plaintiff fail to cite to any case law in this regard, but his testimony in this matter makes clear that his opinions in this case were based in large part on the NTSB findings. *See* Laumbach Dep. 1 at 68, attached to Def. Mem. at Exhibit A, (Q: "the [NTSB Final] report provided information that you relied upon to support your conclusions? A: . . . Yes.") The prejudicial nature of such statements and opinions cannot be overstated.

B. Dr. Laumbach's Declaration Should Be Stricken, As It Improperly Seeks To Correct Errors Of Omission In His Initial Reports.

In what is tantamount to an admission that his original opinions were insufficient to pass muster under *Daubert* and its progeny, Plaintiff's Opposition is supported by a twelve (12) page, single-spaced declaration of Dr. Laumbach. When fairly read, the declaration is really a supplemental expert report, submitted without leave of court, which seeks to improperly inject new grounds and medical literature supporting his opinion - significantly only after his deposition and Defendants' motion revealed substantial flaws with his methodology. Such a tactic unfairly prejudices Defendants and violates both the letter and spirit of this Court's scheduling orders, as well as Fed. R. Civ. P. 26(e).

Dr. Laumbach's declaration constitutes nothing more than an impermissible attempt to strengthen his existing opinion and bolster his inadequate and incomplete report. While Fed. R. Civ. P. 26(e) recognizes that parties have an obligation to supplement expert reports in a timely manner, if the party learns that in some material respect the report is incomplete or incorrect, such supplemental disclosures are "only for the narrow purpose of correcting inaccuracies or adding information that was not available at the time of the initial report. . . ." *Sancom, Inc. v.*

Quest Comm. Corp., 683 F.Supp.2d 1043, 1062-63 (D.S.D. 2010). A supplemental report may be rejected where it is offered to rebut an argument raised in a motion, or was served merely because a party simply wished to supplement. *See, e.g., In re TMI Litig.*, 193 F.3d 613 (3d Cir. 1999) (upholding the exclusion of supplemental expert reports - including some that were submitted in response to motions *in limine* - as untimely); *Collier v. Bradley Univ.*, 113 F. Supp. 2d 1235, 1242 (C.D. Ill. 2000) (striking supplemental expert report submitted in opposition to defendant's *in limine* motion because additional information should have been included in original report). To permit such unfettered supplementation "would create a system where preliminary reports could be followed by supplementary reports and there would be no finality to expert reports, as each side, in order to buttress its case or position, could 'supplement' existing reports and modify opinions previously given." *Beller v. United States*, 221 F.R.D. 696, 701 (D.N.M. 2003). All of this would also interfere with the Court's ability to set case management deadlines, "because new reports and opinions would warrant a new round of consultation with one's own expert and virtually require new rounds of depositions." *Id.* at 701-02.

Here, Dr. Laumbach's declaration is not an attempt to remedy inadvertent factual errors or amend his report based on information not previously available to him. Rather, he is specifically trying to fill the numerous gaps in his reports that were exposed during his deposition and Defendants' motion to exclude him. As a result, his declaration should be stricken from the record pursuant to Rule 26(e) and this Court's Scheduling Orders.

C. Dr. Laumbach's Methodology is Not Generally Accepted.

In an attempt to demonstrate that Dr. Laumbach's methodology and opinions are reliable under *Daubert* and its progeny, Plaintiff simply states that "Dr. Laumbach used a well-established and generally accepted methodology" - as if the fact that Plaintiff alleges it makes it

so. Pl. Opp. at 2. Curiously, Plaintiff contends that “the Bradford Hill factors do not apply”, Pl. Opp. at 7, while simultaneously asserting that Dr. Laumbach followed the Bradford Hill factors in assessing causation.¹ Cf. Laumbach Rep. at 1 (“[My] methodology includes assessment of the Bradford-Hill factors as they apply to evaluation of causation.”). Such contradiction indicates Dr. Laumbach’s inherent lack of a methodology in this matter.

Although Plaintiff cites to a number of cases for the proposition that a strong temporal relationship and immediate symptomology can support a conclusion of causation, those cases are distinguishable from the instant case. See, e.g., *Cavallo v. Star Enter.*, 892 F. Supp. 756 (E.D. Va. 1995). As Sir Bradford Hill stated, “if specificity exists we may be able to draw conclusions without hesitation.” See Hill, A. B. (January 01, 1965). The Environment And Disease: Association Or Causation?; Proceedings of the Royal Society of Medicine, 58, 295-300. However, here, there is no specificity of association, or single cause, of the injuries alleged. Accordingly, application of the Bradford Hill criteria is necessary and appropriate to determining if there is another way of explaining the set of facts present in this case.

Finally, it is worth noting that in their opening memorandum, Defendants clearly established that Dr. Laumbach’s opinions were premised upon inadequate data and faulty assumptions contrary to the circumstances surrounding the derailment. Plaintiff wholly failed to address this argument, instead dismissing them out of hand with statements such as “there is no need to discuss Defendants’ pointless attack on the ALOHA model.” Pl. Opp. at 4. In fact, given Dr. Laumbach’s extensive reliance on the ALOHA model, Defendants’ attack was far from pointless. The ALOHA model was not an actual reflection of the alleged exposures, but instead, a “worst case” modeling that did not incorporate the actual conditions at the time of the

¹ Plaintiff seems to have adopted this ill-fitting argument, as well as the vast majority of his brief, from the Opposition to Defendants’ Motion to exclude Dr. Osinubi in related derailment cases.

derailment. Indeed, the recurring theme of Plaintiff's Opposition is to blankly discredit Defendants' points, perhaps in the hope that this Court will do the same. However, as part of its role as gatekeeper, the district court must ensure that the underlying facts and/or data upon which a proffered expert's opinion are based are reliable in and of themselves. If an expert's opinion is based on unreliable facts, the opinion must be excluded. *See In re TMI Litig.*, 193 F.3d at 697.

D. Temporal Relationship, Without More, Fails To Establish Causation.

Defendants do not dispute that a limited amount of vinyl chloride was released following the derailment. However, merely documenting the existence of vinyl chloride does not prove actual exposure to Plaintiff, nor does it prove that Plaintiff received a sufficient dose to cause or exacerbate his alleged injuries, or increase his risk of cancer. Causation requires a showing of exposure and dose levels sufficient to cause the injuries claimed. *Allen v. Pennsylvania Eng'g Corp.*, 102 F.3d 194, 199 (5th Cir. 1996); *Wright v. Willamette Indus., Inc.*, 91 F.3d 1105, 1107 (8th Cir. 1996); *Amorgianos v. National Railroad Passenger Corp.*, 137 F. Supp. 2d 147, 163 (E.D.N.Y. 2001) (finding that in a toxic tort case, expert testimony on general causation must include testimony on exposure, dose, duration and causation to satisfy *Daubert*).

Nevertheless, Plaintiff contends that “[c]ausation can be established in the absence of a precise measurement.” Pl. Opp. at 5. Among other cases, Plaintiff clings to *Kannankeril v. Terminix Int'l. Inc.*, 128 F.3d 802, 809 (3rd Cir. 1997), and advocates an overly broad and unfounded interpretation of that case. *Kannankeril* does not stand for the blanket proposition that there is no need to show the precise level of exposure to prove causation. The *Kannankeril* Court explicitly noted that the physician there had “sufficient knowledge of exposure” because he reviewed and considered application records for the pesticide which showed when, how much, and where the pesticide had been applied. *Id.* at 808. The plaintiff’s exposure from the repeated

pesticide applications inside the *Kannankeril* home was far more readily inferred than Plaintiff's unknown exposures here in an outdoor setting where there were numerous variables at play (i.e. wind, terrain, atmospheric conditions, Plaintiff's alleged location, etc.). Moreover, general causation was not disputed in *Kannankeril*, and plaintiff developed toxic effects of the pesticide that were "well recognized by the scientific community." *Id.* at 809. Additionally, in *Kannankeril*, the court relied on the fact that the defendant never raised any other theories of causation to challenge the expert's opinion. *Id.* at 808. Here other viable theories of causation have been raised by Defendants. Accordingly, Plaintiff's reliance on *Kannankeril* is misplaced.

Likewise, Plaintiff's reliance upon the perceived temporal relationship between Plaintiff's alleged exposure and onset of injury or symptoms cannot fill the gaping analytical void in Dr. Laumbach's analysis. Admittedly, as a part of the causation picture, an expert may draw conclusions about the effects of exposure to a chemical based upon the temporal connection between exposure and the onset of symptoms. *Heller v. Shaw Indus.*, 167 F.3d at 146, 158 (3d Cir. 1999). However, temporal relationship may not supplant scientifically reliable data supporting the relationship -- the ultimate conclusion, must always fit the data that allegedly supports it. *Id.* In this case, not only does Dr. Laumbach have no data supporting his opinions that Plaintiff's brief and acute exposure to vinyl chloride or its decay products could or did cause Plaintiff's injuries, but the wealth of scientific data manifestly refutes that such limited and acute exposures could cause the alleged injuries. *See* Weed Declaration, attached to Def. Mem. Accordingly, Plaintiff's claims that he was injured, or that any existing maladies were exacerbated after the derailment, do not suffice as a scientifically reliable basis for concluding that the alleged exposures were the cause. Instead of reasoning from known facts to reach a conclusion, Dr. Laumbach has reasoned from an end result in order to hypothesize what was

unknown. He assumes that Plaintiff's injuries were caused by his alleged vinyl chloride exposure, and back-fills this assumption with the hypothesis that the temporal proximity between the development of the injuries and the alleged exposure proves a connection between these events. His opinions are nothing more than unsupported speculation that must be excluded from evidence under Rule 702 and *Daubert*.

E. A Causation Opinion Cannot Be Untethered To Any Scientific Evidence.

To explain the lack of published literature linking the alleged exposures to Plaintiff's alleged injuries, Plaintiff cites *Heller*, 167 F.3d at 155, for the proposition that in certain instances, a medical expert need not cite published studies on general causation to make a reliable causation determination. Pl. Opp. at 11. However, the *Heller* court stated that some basis must be given to support the causation testimony. 167 F.3d at 157-159. The plaintiff's expert, who had identified no literature and had not eliminated other potential causes, was relying solely on a temporal connection. *Id.* Ultimately, the court held that the expert was properly excluded, reasoning that his methodology was "based on speculation and estimation," and none of his assumptions appeared to be "supported by reliable scientific methods or the reliable application of any valid theory." *Id.* at 162-63. Accordingly, Plaintiff cannot save Dr. Laumbach's causation opinion as to acute vinyl chloride exposure and long-term respiratory disease (as opposed to brief respiratory discomfort) by relying on studies discussing "short term respiratory effects," and analogizing to studies of other "respiratory irritants." Likewise, in the absence of literature supporting his opinions and a proper differential diagnosis, Dr. Laumbach's general causation and medical monitoring opinions, next discussed, are similarly speculative and unreliable.

F. Dr. Laumbach's Risk-Of-Cancer and Medical-Monitoring Opinions Lack Support And Are Therefore Inadmissible.

Despite the fact that Dr. Laumbach admitted that there is no scientific evidence linking acute vinyl chloride exposure to increased cancer prevalence in humans, *see* Laumbach Dep. Ex. 18 (attached to Def. Mem.), Plaintiff continues to attempt to exploit prophylactic regulatory and advisory standards to support Dr. Laumbach's general causation and medical monitoring opinions. Pl. Opp. at 12-13. As the Railroad Defendants set forth in their opening brief, courts around the country have refused to rely on such standards because “[r]egulatory and advisory bodies such as IARC, OSHA and EPA” use a “threshold of proof [that] is reasonably lower than that appropriate in tort law” when making “prophylactic rules.” *Allen*, 102 F.3d at 198 (quoting *Wright*, 91 F.3d at 1107). To the authorities the Railroad Defendants cited in their opening brief that support this rule, Plaintiff provides no response.

The National Academy of Sciences (“Academy”) calculations and EPA risk assessments on which Plaintiff and Dr. Laumbach rely (Laumbach Decl. ¶¶ 16, 23) “intentionally encompass the upper range of possible risks,” and “do not provide information about actual risk or causation.” *Gates v. Rohm & Haas Co.*, 265 F.R.D. 208, 226-27 (E.D. Pa. 2010) (citation omitted).² Moreover, the Academy expressly cautions that “there is great uncertainty in those estimates, and they conflict with epidemiologic data on occupational exposure to VC,” a fact Dr. Laumbach fails to acknowledge in his declaration. Committee on Acute Exposure Guideline Levels, *Acute Exposure Guideline Levels for Selected Airborne Chemicals: Volume 11* at 259

² The same is true of the OSHA “action levels” Plaintiff cites, Pl. Opp. at 12, and the Acute Exposure Guideline Levels (AEGLs) upon which Dr. Laumbach relies. *See Nat'l Bank of Commerce v. Associated Milk Producers, Inc.*, 22 F. Supp. 2d 942, 961 (E.D. Ark. 1998), aff'd, 191 F.3d 858 (8th Cir. 1999) (holding that “regulatory agencies employ a different perspective in setting ‘action levels’ than do courts imposing tort liability); *Johnson v. Arkema, Inc.*, 685 F.3d 452, 463-64 (5th Cir. 2012) (recognizing that AEGLs, like other regulatory standards, “are not necessarily reliable in all toxic tort cases,” and holding that, in failing to provide the underlying basis for the experts’ reliance on them, the experts’ opinions are inadmissible).

(2012), available at http://www.epa.gov/opptintr/aegl/pubs/vinyl_chloride_volume_11.pdf. In sum, these regulatory standards and exposure levels “are inappropriate for use in determining whether medical monitoring should be instituted” because they “overstate the *actual* risk.” See *O’Neal v. Dep’t of the Army*, 852 F. Supp. 327, 333 (M.D. Pa. 1994).³

In his Declaration, Dr. Laumbach relies on a 1998 study of 29 individuals exposed to vinyl chloride after a 1996 train derailment, explosion, and fire in Germany. See Pl. Opp. at 14; Laumbach Decl. ¶ 21 (referencing E. Huttner, T. Nikolova, *Cytogenetic analysis of peripheral lymphocytes in a population exposed to vinyl chloride through an accidental release into the environment*, Toxicol. Lett. 96/97 (1998) 143-48 (attached as Exhibit 2)). Dr. Laumbach’s reliance on that study is unfounded. First, there is no evidence that the type of genetic changes discussed in that study are associated with a significant increased risk of liver cancer. Second, and even more tellingly, Dr. Laumbach is unaware of a later study by many of the same authors involving the same exposed and control populations that found no significant difference in the frequency of mutations in the HPRT gene. See R. Becker, T. Nikolova, I. Wolff, D. Lovell, E. Huttner, H. Foth, *Frequency of HPRT mutants in humans exposed to vinyl chloride via an environmental accident*, Mutation Research 494 (2001) 87-96 (attached as Exhibit 3); see also Laumbach Decl. ¶ 21 (“To my knowledge there have been no reports of following-up on cancer

³ Plaintiff takes out of context the fact that Dr. Greenberg, the Railroad Defendants’ medical expert and toxicologist, used the EPA algorithm to calculate a “theoretical increased risk of cancer” based on vinyl chloride levels observed after the Paulsboro derailment. See Pl. Opp. at 13 n.7; see also Greenberg General Causation Report at 22 (attached as Exhibit 1). As Dr. Greenberg makes quite clear in his report: “For the purposes of risk assessment, it is possible to calculate ***the theoretical increased risk of cancer*** from an acute duration exposure ***despite the evidence in occupational studies that short-term exposure to vinyl chloride does not increase the prevalence of tumors.***” Greenberg Rep. at 22. (emphasis added). Dr. Greenberg’s calculations demonstrate that not even these theoretical and highly-protective regulatory risk estimates suggest that the acute exposure levels observed in Paulsboro would increase the risk of liver cancer. *Id.*

risk in this population.”). Although it has now been almost twenty years since the 1996 derailment, there is no epidemiological data suggesting a higher incidence of cancer (or known mutations that lead to liver cancer) in that exposed group—a critical fact that Dr. Laumbach did not consider in formulating his opinion.

Dr. Laumbach again relies in his declaration on a 1981 animal study, which he misleadingly characterizes as “a study of mice.” Laumbach Decl. at 22. As the Railroad Defendants set forth in their opening brief, that study demonstrates dramatically different results in the animal species tested: the exposed mice developed pulmonary adenomas but the exposed rats did not. *See Robert M. Hehir, et al., Cancer Induction Following Single Multiple Exposures to a Constant Amount of Vinyl Chloride Monomer*, 41 Envtl. Health Persp. 71 (1981) (attached as Exhibit 4) (“In our studies, Fischer rats were exposed to a total dosage of 50, 500, 5000, and 50,000 ppm VC for 1 hr showed no chemically induced tumor response.”). Despite attempting to supplement his report with a lengthy declaration, Dr. Laumbach does not address this distinction; nor does he make any attempt to explain why an increase in pulmonary adenomas with progression to lung cancer in exposed mice (but not rats) demonstrates an increased risk of liver cancer in humans. That Dr. Laumbach would nonetheless still rely on the 1981 study underscores the unreliability of his opinion. *See Allen*, 102 F.3d at 197 (rejecting an expert’s reliance on an animal study that showed brain cancer after chemical exposure in rats but not mice because the rats’ response could not even predict how a mouse would react to chemical exposure, let alone humans); *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 743 (3d Cir. 1994) (“[I]n order for animal studies to be admissible to prove causation in humans, there must be good grounds to

extrapolate from animals to humans, just as the methodology of the studies must constitute good grounds to reach conclusions about animals themselves.”).⁴

In again conflating acute and chronic exposure, Dr. Laumbach misleadingly states in his declaration that “the causal association between vinyl chloride and angiosarcoma of the liver and hepatocellular carcinoma does not appear to be in dispute in this matter.” Laumbach Decl. ¶ 7. On the contrary, the Railroad Defendants have consistently pointed out—and Dr. Laumbach has even admitted—that there is no evidence linking acute vinyl chloride exposure to an increased risk of cancer. *See* Weed Decl. at 35 (attached to Def. Mem.) (“A causal relationship between vinyl chloride and angiosarcoma of the liver in human populations has only ever been observed in occupational groups involving the manufacture and production of vinyl chloride.”).

In a transparent attempt to minimize the importance of this lack of evidence, Dr. Laumbach characterizes the critical distinction between acute and occupational exposure as “false.” Laumbach Decl. ¶ 6.f. Yet, as Dr. Laumbach himself concedes, occupational exposures “are generally of higher intensity than [sic] community exposures.” *Id.* Moreover, “[e]xtremely high levels of cumulative exposure to vinyl chloride—in terms of ppm-years of cumulative exposure—are needed to cause HCC [hepatic cell carcinoma].” Weed Decl. at 35. Far from being false, the distinction between acute and chronic exposure is critical in assessing the risk of cancer stemming from the derailment and chemical release.

Last, Dr. Laumbach’s belated attempt to demonstrate that the medical monitoring he proposes is medically necessary fails. *See* Laumbach Decl. ¶ 26. Dr. Laumbach has not provided

⁴ Dr. Laumbach also makes passing reference to the World Trade Center disaster, stating, without providing context, that “[t]he nature of the Paulsboro derailment is similar.” *See* Laumbach Decl. ¶ 20. The WTC disaster is simply not comparable to the Paulsboro derailment and chemical release, and so the fact that certain WTC First Responders may be entitled to medical monitoring is irrelevant.

any support for his opinion, and his “say so” is wholly insufficient. *See Saldo v. Sandoz Pharm. Corp.*, 244 F. Supp. 2d 434, 563 (W.D. Pa. 2003) (holding that the court “is not required simply to ‘take the expert’s word for it’”). In the absence of any peer-reviewed study showing that the specific medical monitoring he recommends is medically beneficial because of acute exposure to vinyl chloride, Dr. Laumbach’s opinion does not withstand the *Daubert* test. *In re Ingram Barge Co.*, 187 F.R.D. 262, 266 (M.D. La. 1999) (rejecting expert testimony on medical monitoring under *Daubert* because the expert “could point to no studies or peer-reviewed literature which suggested that the testing and monitoring he recommends should be performed”).

III. CONCLUSION

For the foregoing reasons, Defendants, Consolidated Rail Corporation, Norfolk Southern Railway Company and CSX Transportation, Inc., respectfully request that this Honorable Court exclude the proffered expert testimony of Robert Laumbach, M.D., M.P.H., C.I.H.

Respectfully Submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of July, 2015, a copy of the within Reply Memorandum of Law in Support of their Motion to Exclude the Expert Report and Testimony of Robert Laumbach, M.D. was served on all counsel of record via efile.

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